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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,072	11/14/2003	Kilian Heitz	FR4-002	2625
959	7590	12/28/2007	EXAMINER	
LAHIVE & COCKFIELD, LLP			LLOYD, EMILY M	
ONE POST OFFICE SQUARE				
BOSTON, MA 02109-2127			ART UNIT	PAPER NUMBER
			3736	
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			12/28/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/714,072	HEITZ, KILIAN
	<b>Examiner</b>	<b>Art Unit</b>
	Emily M. Lloyd	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on 14 November 2003 and 02 May 2006.
- 2a)  This action is FINAL. 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 22-42 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 22-42 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 02/25/2004 and 06/27/2007.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Information Disclosure Statement***

1. The information disclosure statement filed 25 February 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Drawings***

2. The drawings are objected to because it is unclear what the word "Trise2" in Figure 2 means. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because the word "means" is used multiple times and the word "contraception" is misspelled on line 2. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: headings are missing (see MPEP 608.01(a) and paragraph 6 of this Office Action); substitute specification page 2 line 26 "as" should be "has"; page 4 line 6 "discharge" should possibly be "discharged"; page 4 line 26 "Subsequent" should be "Subsequently the"; the paragraph starting at the bottom of page 5 and the third paragraph on page 7 refer to cancelled claim 1; line 4 of the fourth full paragraph on page 9 should likely say something like "providing contraception" instead of "preventing contraception"; page 13 the figure descriptions of Figures 2 and 4 should be revised for clarity and the

description of Figure 5 is incorrect as Figure 6 shows the back of the device (see the paragraph starting on the bottom of page 16); and line 15 of the only full paragraph on page 16 should refer to Figure 6 instead of Figure 2.

Appropriate correction is required.

6. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Claim Objections***

7. Claims 22-42 are objected to because of the following informalities: Claim 22 line 1 a colon should follow "comprising", and line 4 "the saliva" and line 10 "the woman's" lack antecedent basis; claim 26 line 2 "of the data" should be added after "weighting" and line 6 "the" should be inserted before "weighting"; claim 26 it is unclear what percentages are being claimed (preferably versus especially preferably); claims 23-30, 32-38, and 40 "characterized in that" should be "wherein"; claims 31 and 39 "characterized by" should be "wherein"; and claims 41 and 42 should be revised to clarify what structure is added or modified and "designed so that" should be "wherein"; claim 41 lines 3-4 should be revised regarding grammar; and claims 34 and 38 to clarify what features are alternatives by the use of "and/or" in claim 34 lines 2 and 4 and claim 38 line 5. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 23-26, 32, 36, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 depends on cancelled claim 1. For the purpose of examination, the Examiner has interpreted claim 23 as depending on claim 22.

Claims 24-26 depend on cancelled claim 2. For the purpose of examination, the Examiner has interpreted claims 24-26 as depending on claim 23.

10. Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The current claims disclose that the data is weighted by type. However, the specification does not disclose the details of how the data is weighted by type that produces the order and percentages of weighted data claimed.

11. Regarding claims 32 and 36, the phrase "for example" or "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

12. Regarding claim 41, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

#### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 22-27, 29, and 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 4465077 (Schneider) as modified by United States Patent 5572370 (Cho).

Regarding claim 22, Schneider discloses a device for family planning or contraception (fertility computer 40 Figure 1), comprising: a means for determining basal temperature (temperature probe 64 Figure 1), a means for input of the first day of the cycle (period entry switch 52 Figure 1), a means for input of the property of a biological fluid (mucus entry switch 50 Figure 1; also optional vaginal probe 108 Figure 2), a device for processing the data made available by the means (microprocessor 9 Figure 2), a memory device for storing at least some of the data made available (RAM (random access memory) storage 13 Figure 2), and a display device (fertility status (FS) LED 56 Figure 1), whereby the device for processing the data is designed such that a conclusion regarding the woman's fertility on any given day is determined as a function of at least some of the data made available by each means (Column 17 line 18 – Column 23 line 46) and this conclusion can be displayed via the display device (fertility status (FS) LED 56 Figure 1, Column 22 lines 23-41).

Schneider discloses the claimed invention except for inputting the property of saliva. Cho teaches the use of the property of saliva for family planning or contraception (apparatus for determining the period of maximum fertility in women,

Figures 1 and 9; also Column 5 lines 9-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the measurement of the property of saliva as taught by Cho in the invention of Schneider to provide the predictable result of providing the a probe "which help[s] detect ovulation by change in biochemical properties" (Schneider Column 26 lines 24-25) as suggested by Schneider and to provide a more convenient property of a biological fluid (the saliva testing of Cho is more convenient than the vaginal mucus testing/reporting of Schneider).

Regarding claim 23, Schneider as modified by Cho teach the device according to claim 22, characterized in that the device for processing the data is designed so that the data is weighted differently in determining the conclusion regarding the woman's fertility (Schneider Column 17 line 18 – Column 23 line 46).

Regarding claim 24, Schneider as modified by Cho teach the device according to claim 23, characterized in that the weighting of the data can be varied as a function of the stored data formerly made available (Schneider Column 18 line 64 – Column 19 line 28; also Column 20 lines 48-52).

Regarding claim 25, Schneider as modified by Cho teach the device according to claim 23, characterized in that the conclusion regarding the woman's fertility depends on the data made available by the means for determining the basal temperature to a greater extent than on the data made available by the means for input of the first day of the woman's cycle (Schneider basal temperature is looked at more in terms of averages and comparisons than that of the first day of the woman's cycle, Column 17 line 18 – Column 23 line 46), and the data made available by the means for input of the first day

of the woman's cycle in turn has a greater influence on the conclusion regarding her fertility than does the data made available by the means for input of the properties of the saliva (Schneider uses the property of a biological fluid after the basal temperature and first day of a woman's cycle, Column 19 lines 52-59; as modified by Cho this would use the properties of the saliva instead of cervical mucus).

Regarding claim 26, Schneider as modified by Cho teach the device according to one of the claim 23, with the ranking of weighting described in claim 25 (see 103(a) rejection of claim 25 above).

Schneider as modified by Cho do not address the exact percentages of the weighting of the data. However, the weightings do reflect the most weight being given to the basal temperature data and the least weight being given to the data from the properties of the saliva, which includes the claimed percentages. Applicant has not disclosed that the claimed percentages solve any stated problem. Moreover, it appears that the weightings in Schneider as modified by Cho's algorithm, or applicant's invention, would perform equally well for women with regular menstrual cycles and for women with irregular menstrual cycles.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Schneider as modified by Cho such that the percentages of the weightings are 50-90% for basal temperature, 5-35% for the first day of the woman's cycle, and 2-20% for the properties of the saliva, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Schneider as modified by Cho.

Regarding claim 27, Schneider as modified by Cho teach the device according to claim 22, characterized in that the device is equipped for processing data, such that the conclusion regarding a woman's fertility differentiates between possible fertile and infertile days and that the possible fertile and infertile days are displayed visually in different ways (Schneider fertility status (FS) LED 56 Figure 1 blinks frequently for fertile days and does not blink on infertile days, Column 22 lines 23-41).

Regarding claim 29, Schneider as modified by Cho teach the device according to claim 27, characterized in that transition days are also provided in the conclusion regarding the woman's fertility; these are days when no distinction is made between possible fertile days and possible infertile days, and the transition days are displayed differently visually than the possible fertile days and infertile days (Schneider fertility status (FS) LED 56 Figure 1 blinks less frequently on transition days, Column 22 lines 23-41).

Regarding claim 31, Schneider as modified by Cho teach the device according to claim 27, characterized by a means for recognizing an increase in temperature (Schneider microprocessor 9 Figure 2) from the data made available by the means for determining the basal temperature (Schneider temperature probe 64 Figure 1), whereby in determining the conclusion regarding the woman's fertility, a distinction is made between a first phase of the cycle at the beginning of the cycle and a second phase of the cycle after the rise in temperature is detected (Schneider Column 23 lines 17-28).

Regarding claim 32, Schneider as modified by Cho teach the device according to claim 31, characterized in that up to a first point in time the number of possible fertile

days is preselected in the conclusion regarding the woman's fertility in the second phase of the cycle (Schneider Column 16 lines 57-68).

Regarding claim 33, Schneider as modified by Cho teach the device according to claim 32, characterized in that after the first point in time, the number of possible fertile days is determined as a function of an analysis of stored data in the conclusion regarding the woman's fertility in the second phase of the cycle (Schneider Column 16 lines 65-68 and Column 17 line 18 – Column 23 line 46).

Regarding claim 34, Schneider as modified by Cho teach the device according to claim 33, characterized in that an indicator for the regularity of the duration of the cycle and/or the course of the cycle is derived from the stored data (Schneider regularity of the duration of the cycle by CL and C(1)-C(12), see table under Column 4), and the number of possible infertile days is determined as a function of this indicator (Schneider use of CL in Section G (Compute Fertility Status) Figure 3j is one example of this; see also Column 17 line 18 – Column 23 line 46) and/or the number of cycles registered by the device (Schneider Column 18 line 64 – Column 19 line 26) is determined in the conclusion regarding the woman's fertility in the second phase of the cycle.

Regarding claim 35, Schneider as modified by Cho teach the device according to claim 31, characterized in that the number of possible fertile days is determined and/or influenced as a function of the data made available by the means for input of the properties of the saliva in the conclusion regarding fertility in the second phase of the cycle (Cho Column 5 lines 9-25).

Regarding claim 36, Schneider as modified by Cho teach the device according to claim 31, characterized in that up to a second point in time the number of possible infertile days is preselected in the conclusion regarding the woman's fertility in the first phase of the cycle (Schneider Column 16 lines 57-68).

Regarding claim 37, Schneider as modified by Cho teach the device according to claim 36, characterized in that after the second point in time, the number of possible infertile days is determined as a function of an analysis of stored data in the conclusion regarding the woman's fertility in the first phase of the cycle (Schneider Column 16 lines 65-68 and Column 17 line 18 – Column 23 line 46).

Regarding claim 38, Schneider as modified by Cho teach the device according to claim 37, characterized in that a quality factor is derived from the stored data (Schneider DF differential value, table above Columns 5 and 6), and after the second point in time, in the conclusion regarding the woman's fertility in the first phase of the cycle, the number of possible infertile days is determined as a function of the quality factor (Schneider use of DF in Section G (Compute Fertility Status) Figure 3j, see also Column 17 line 18 – Column 23 line 46) and/or the number of periods registered by the device is determined as a function of some data from the means for input of the first day of the cycle.

Regarding claim 39, Schneider as modified by Cho teach the device according to claim 22, characterized by a time measuring device (Schneider programmable timer 11 Figure 2) and an interactive device (Schneider space 5 Figure 1 and Column 6 lines 52-

53) for instructing a user to input data after a predetermined period of time has elapsed (Schneider Column 25 lines 62-64).

Regarding claim 40, Schneider as modified by Cho teach the device according to claim 39, characterized in that the interactive device is designed so that an input of the properties of the saliva is instructed 5-10 times per cycle (Schneider teaches prompting for the collection of data (see Column 25 lines 62-64), Cho teaches that the saliva indicates fertility for approximately 5 to 7 days (Column 5 lines 25-28)). It would have been obvious to instruct the input of the properties of saliva 5-10 times per cycle in the invention of Schneider as modified by Cho to allow for additional data to confirm transition and fertile days with the testing dates indicated by the other parameters disclosed by Schneider.

Regarding claim 41, Schneider as modified by Cho teach the device according to claim 22, designed so that fluctuations in temperature that are not due to the cycle but instead are caused by other factors such as a cold or a migraine are recognized (Schneider Column 12 lines 50-58 and 18-22) and then this data is discarded when determining the possible fertile and/or infertile days (Schneider Column 12 lines 58-60).

Regarding claim 42, Schneider as modified by Cho teach the device according to claim 22, designed so that a cycle and in particular the duration and/or the course of the cycle are recognized (Schneider duration of the cycle by CL and C(1)-C(12), see table under Column 4).

16. Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider as modified by Cho as applied to claims 22-27, 29, and 31-42 above, and further in view of United States Patent 5657762 (Coley et al.).

Regarding claims 28 and 30, Schneider as modified by Cho teach the device according to claims 27 and 29. Schneider as modified by Cho teach that fertile days, infertile days, and transition days are displayed visually in different ways (see 103(a) rejections of claims 27 and 29 above). Schneider as modified by Cho do not teach that the display device shows possible fertile days in red, possible infertile days in green, and transition days in yellow. Coley et al. teach a display device that shows possible fertile days in red, possible infertile days in green, and transition days in yellow (Column 4 lines 32-39, Column 6 lines 20-23, and the bottom of Figure 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such color indicators of fertility as taught by Coley et al. in the invention of Schneider as modified by Cho to provide the predictable result of conveying "information on the state of fertility ... by a simple visual indication" (Coley et al. Column 4 lines 34-35).

### ***Conclusion***

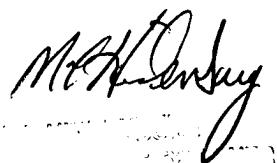
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd  
Examiner  
Art Unit 3736

/EML/

A handwritten signature in black ink, appearing to read "Emily M. Lloyd".